



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/621,146	07/21/2000	Chryslain Sumian	BJA 254A	3940

7590 08/23/2004
Bolesh J Skutnik PhD JD
515 Shaker Road
East Longmeadow, MA 01028

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/621,146	SUMIAN, CHRYSLAIN	
	Examiner	Art Unit	
	Gollamudi S Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Upon consideration, the election requirement as set forth in the previous action is withdrawn.

Claims included in the prosecution are 1-2 and 5-20.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-2 and 5-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There are three figures in the specification and in the brief description of figures 2 and 3 apparently deal with the hair follicle reaction after a swellable composition is applied. However, nowhere in the specification one can find what swellable composition is applied. In fact, with regard to swellable composition, the specification only refers to some prior art and does not specifically disclose what compositions come under swellable compositions. In fact, on page 8 of the specification state, "In one preferred embodiment, the substance is a form of microsphere or liposome. As disclosed in EP 03750520 and WO 98/48716, formulations containing specific size of ingredients (e.g. microspheres or liposomes) may target

Art Unit: 1615

compounds to follicles". First of all, according to instant claim 18, the polymers are encapsulated in liposomes whereas according to applicant's statement above refers to the 'substance *is a* form of liposomes'. This means the liposome itself is a swellable composition. These two concepts are totally different. There is no guidance provided in the specification for either of the concepts for one of ordinary skill in the art to practice the invention without undue experimentation. Secondly there is no EP patent with the number recited. Thirdly, according to the English equivalent of the WO reference cited (US 6,287,549) the microspheres are made from even fatty substances (WO is one of the references which applicant recites as a guidance for the selection of swellable composition) such as fatty alcohols and triglycerides for the preparation of microspheres (col. 2, line 63 through col. 3, line 2). These are lipophilic compounds (water repellants) and it is unclear as to how they can swell within the follicles. According to col. 3, lines 3-5 of US 6,287,549, "vesicular microparticles may also be used as liposomes and, preferably, polymerized liposomes whether reverse or forward". This statement clearly implies that liposomes themselves are microparticles and not that the polymers are within the liposomes. In essence, instant specification does not provide adequate guidance to one of ordinary skill in the art as to which swellable compounds come under the definition of swellable compositions or how to use liposomes in practicing the invention without undue experimentation.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1615

4. Claims 10, 11, 12, 16 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what applicant intends to convey by 'compounds/drugs are molecules and their derivatives used in cosmetic/pharmaceutical applications' in claim 10. The use of the term, 'derivative' would only be appropriate if a specific compound is recited' and not 'molecule'. Secondly, does it mean that the expression, "compounds/drug" in the parent claim 1 includes even those, which have no cosmetic/pharmaceutical applications?

It is unclear as to what applicant intends to convey by 'photosensitizer molecules, their derivatives and their precursors used in photodynamic therapy' as recited in claim 11. If the derivatives and precursors have photosensitizing property, then they also come under the category of 'photosensitizer molecules'. The examiner suggests the deletion of ', their derivatives and their precursors'.

Claim 12 specifies that the swellable composition of claim 1 to be cosmetically/pharmaceutically acceptable. Does this mean that the composition of claim 1 includes even cosmetically/pharmaceutically non-acceptable compositions?

It is unclear as to what applicant intends to convey by 'polymers are encapsulated' in claim 16. Does applicant mean that the polymers are in the form of microspheres? That is what is conveyed in the specification. Similar is the case with

Art Unit: 1615

'polymers are encapsulated in liposomes" as recited in the specification. There is inadequate description of this expression in the specification.

It is unclear what applicant intends to convey by "swelling composition is covered during said volume swelling, and whereby horizontal swelling of said swelling composition is favored against vertical swelling. Is the skin area is covered or swelling composition is covered? Secondly, a hair follicle is three-dimensional and when a swelling composition is applied, naturally it will penetrate the follicle and swell both horizontally and vertically filling up the interior of the follicle. The terminology is confusing.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-2, 5-8 and 10-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S.

Patent No. 6,287,549. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Art Unit: 1615

The claims in the patented claims and instant claims are drawn to a method of applying the same composition, that is, particles of the same swellable polymers containing the active agents. Instant steps a and b in claim 1 correspond to step a in claims 1 and 17 of said patent. Although instant step b is not specified in the patented claims 1 and 17, such is implicit since the purpose in the patented invention is the same, that is, letting the active agent chromophores (photosensitizers) penetrate the follicles. Although patented claims do not recite the step of 'volume swelling' (instant step c) such is again implicit since the swelling is the property of the polymer microspheres and the chromophores in the invention do penetrate and enters the cells. Instant claim language does not exclude the laser treatment step recited in the patented claims. Instant pretreatment steps of removing the hair or cutting the hair as recited in claims 6 and 7 are obvious steps one practices for maximum penetration of the active agent into the follicles.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-2, 5, 8 and 10-18 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/48716 of record (English equivalent: US 6,287,549).

WO teaches a method wherein a swellable polymeric particle or polymeric liposomal composition containing chromophores

Art Unit: 1615

(phthalocyanins) is applied onto the skin. Since the composition in WO is the same as in instant application, instant steps, instant steps b and c are inherent in prior art; since the same polymers are used they would swell the same way in instant method and the method in the prior art (see abstract, col. 2, line 45 through col. 3, line 50, col. 5, lines 62-67 and claims).

9. Claims 1-2, 5, 8 and 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaefer (5,292,512) of record.

Schaefer teaches a method wherein a swellable polymeric particle composition containing various active agents is applied onto the skin for selective entry into follicles. The composition is applied to the skin with a gentle massage. Since the composition in Schaefer is the same as in instant application, instant steps, instant steps b and c are inherent in prior art; since the same polymers are used they would swell the same way in instant method and the method in the prior art (see abstract, col. 2, line 5 through col. 4, line 54, col. 5, line 1 through col. 8, line 35, Examples and claims).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 6-7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48716 of record (English equivalent: US 6,287,549) cited above.

Art Unit: 1615

The teachings of WO have been discussed above. What is lacking in WO is the teaching of the removal of hair before application of the swellable composition. However, since the purpose of the method is to make the active agent in the composition to penetrate the follicles, it is within the skill of the art to realize that the maximum penetration occurs when the hairs are shaved or cut before the application of the composition. WO does not provide specific examples showing the method using the liposomes (there are no examples in instant specification either). However, in view of the guidance provided by WO, it is deemed obvious to one of ordinary skill in the art to use liposomes with a reasonable expectation of success.

12. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer cited above.

The teachings of Schaefer have been discussed above. What is lacking in Schaefer is the teaching of the removal of hair before application of the swellable composition. However, since the purpose of the method is to make the active agent in the composition to penetrate the follicles, it is within the skill of the art to realize that the maximum penetration occurs when the hairs are shaved or cut before the application of the composition.

13. Claims 6-7, 9 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48716 of record (English equivalent: US 6,287,549) cited above, further in view of Li (5,914,126).

The teachings of WO have been discussed above. As pointed out above, what is lacking in WO is the teaching of the removal of

Art Unit: 1615

hair before application of the swellable composition. What is also lacking in WO is the teaching of the occlusion of the area wherein the composition was applied with a cover.

Li while disclosing liposomal compositions for the delivery of the active agents to hair follicles teaches preshaving of the area to be treated and subsequent band-aid patch to immobilize the composition onto the skin to prevent evaporation (abstract, col. 41, line 62 through col. 42, line 2 and claims).

Preshaving of the skin and the occlusion of the area where the composition was applied would have been obvious to one of ordinary skill in the art since these are routinely practiced in the art as evident from Li. One of ordinary skill in the art would be motivated further to use liposomes, since liposomes are sustained release compositions and have been used in the art for the delivery of active agents as evident from Li.

14. Claims 6-7, 9 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer cited above, further in view of Li (5,914,126).

The teachings of Schaefer have been discussed above. As pointed out above, what is lacking in Schaefer is the teaching of the removal of hair before application of the swellable composition. What is also lacking in Schaefer is the teaching of the occlusion of the area wherein the composition was applied with a cover.

Li while disclosing liposomal compositions for the delivery of the active agents to hair follicles teaches preshaving of the area to be treated and subsequent band-aid patch to immobilize the composition onto the skin to prevent evaporation (abstract, col. 41, line 62 through col. 42, line 2 and claims).

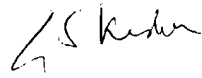
Art Unit: 1615

Preshaving of the skin and the occlusion of the area where the composition was applied would have been obvious to one of ordinary skill in the art since these are routinely practiced in the art as evident from Li.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK